

## General Assembly

## **Amendment**

January Session, 2005

LCO No. 6745

\*SB0093406745SD0\*

Offered by:

SEN. MURPHY, 16<sup>th</sup> Dist. REP. SAYERS, 60<sup>th</sup> Dist. SEN. LEBEAU, 3<sup>rd</sup> Dist. REP. BERGER, 73<sup>rd</sup> Dist.

To: Subst. Senate Bill No. 934

File No. 446

Cal. No. 348

## "AN ACT PERMITTING STEM CELL RESEARCH AND BANNING THE CLONING OF HUMAN BEINGS."

- Strike everything after the enacting clause and substitute the
- 2 following in lieu thereof:
- 3 "Section 1. (NEW) (Effective from passage) (a) As used in this section
- 4 and section 19a-32c of the general statutes, as amended by this act, and
- 5 sections 3 and 4 of this act:
- 6 (1) "Institutional review committee" means the local institutional
- 7 review committee specified in 21 USC 360j(g)(3)(A)(i), as amended
- 8 from time to time, and, when applicable, an institutional review board
- 9 established in accordance with the requirements of 45 CFR 46, Subpart
- 10 A, as amended from time to time.
- 11 (2) "Cloning of a human being" means inducing or permitting a
- 12 replicate of a living human being's complete set of genetic material to

- 13 develop after gastrulation commences.
- 14 (3) "Gastrulation" means the process immediately following the 15 blastula state when the hollow ball of cells representing the early 16 embryo undergoes a complex and coordinated series of movements 17 that results in the formation of the three primary germ layers, the 18 ectoderm, mesoderm and endoderm.
- 19 (4) "Embryonic stem cells" means cells created through the joining of 20 a human egg and sperm or through nuclear transfer that are 21 sufficiently undifferentiated such that they cannot be identified as 22 components of any specialized cell type.
- 23 (5) "Nuclear transfer" means the replacement of the nucleus of a 24 human egg with a nucleus from another human cell.
  - (6) "Eligible institution" means (A) a nonprofit, tax-exempt academic institution of higher education, (B) a hospital that conducts biomedical research, or (C) any entity that conducts biomedical research or embryonic or human adult stem cell research.
  - (b) No person shall knowingly (1) engage or assist, directly or indirectly, in the cloning of a human being, (2) implant human embryos created by nuclear transfer into a uterus or a device similar to a uterus, or (3) facilitate human reproduction through clinical or other use of human embryos created by nuclear transfer. Any person who violates the provisions of this subsection shall be fined not more than one hundred thousand dollars or imprisoned not more than ten years, or both. Each violation of this subsection shall be a separate and distinct offense.
  - (c) (1) A physician or other health care provider who is treating a patient for infertility shall provide the patient with timely, relevant and appropriate information sufficient to allow that person to make an informed and voluntary choice regarding the disposition of any embryos or embryonic stem cells remaining following an infertility treatment.

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(2) A patient to whom information is provided pursuant to subdivision (1) of this subsection shall be presented with the option of storing, donating to another person, donating for research purposes, or otherwise disposing of any unused embryos or embryonic stem cells.

- (3) A person who elects to donate for stem cell research purposes any human embryos or embryonic stem cells remaining after receiving infertility treatment, or unfertilized human eggs or human sperm shall provide written consent for that donation and shall not receive direct or indirect monetary payment for such human embryos, embryonic stem cells, unfertilized human eggs or human sperm.
- (4) Any person who violates the provisions of this subsection shall be fined not more than fifty thousand dollars or imprisoned not more than five years, or both. Each violation of this subsection shall be a separate and distinct offense.
- (d) A person may conduct research involving embryonic stem cells, provided (1) the research is conducted with full consideration for the ethical and medical implications of such research, (2) the research is conducted before gastrulation occurs, (3) prior to conducting such research, the person provides to the Commissioner of Public Health documentation verifying that any human embryos, embryonic stem cells, unfertilized human eggs or human sperm used in such research have been donated voluntarily in accordance with the provisions of subsection (c) of this section, on a form and in the manner prescribed by the Commissioner of Public Health, (4) the general research program under which such research is conducted is reviewed and approved by an institutional review committee, as required under federal law, and (5) the specific protocol used to derive stem cells from an embryo is reviewed and approved by an institutional review committee.
- (e) The Commissioner of Public Health shall enforce the provisions of this section and may adopt regulations, in accordance with the provisions of chapter 54 of the general statutes, relating to the

administration and enforcement of this section. The commissioner may request the Attorney General to petition the Superior Court for such order as may be appropriate to enforce the provisions of this section.

- Sec. 2. Section 19a-32c of the general statutes is repealed and the following is substituted in lieu thereof (*Effective from passage*):
- 81 (a) There is created a Biomedical Research Trust Fund which shall 82 be a separate nonlapsing fund. The trust fund may accept transfers 83 from the Tobacco Settlement Fund and may apply for and accept gifts, 84 grants or donations from public or private sources to enable the 85 account to carry out its objectives. [On and after July 1, 2001, the] The 86 Commissioner of Public Health, in consultation with the Secretary of 87 the Office of Policy and Management, may make grants-in-aid from 88 the trust fund to eligible institutions for the purpose of funding 89 biomedical research in the fields of heart disease, cancer and other 90 tobacco-related diseases, and embryonic and human adult stem cell 91 research. [For the fiscal year ending June 30, 2002, the total amount of 92 such grants-in-aid made during the fiscal year shall not exceed two 93 million dollars. For the fiscal year ending June 30, 2003, and each fiscal 94 year thereafter, the total amount of such grants-in-aid made during the 95 fiscal year shall not exceed fifty per cent of the total amount held in the 96 trust fund as of the date such grants-in-aid are approved. Not later 97 than April 1, 2001, the Commissioner of Public Health shall develop an 98 application for grants-in-aid under this section and may receive 99 applications from eligible institutions for such grants-in-aid on and after said date. For purposes of this section, "eligible institution" means 100 101 (1) a nonprofit, tax-exempt academic institution of higher education, or 102 (2) a hospital that conducts biomedical research.]
  - (b) Not later than June 30, 2006, the Stem Cell Research Advisory Committee established pursuant to section 3 of this act shall develop an application for grants-in-aid under this section for the purpose of conducting embryonic or human adult stem cell research and may receive applications from eligible institutions for such grants-in-aid on and after said date. The Stem Cell Research Advisory Committee shall

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require any applicant for a grant-in-aid under this section to conduct stem cell research to submit (1) a complete description of the applicant's organization, (2) the applicant's plans for stem cell research and proposed funding for such research from sources other than the state of Connecticut, and (3) proposed arrangements concerning financial benefits to the state of Connecticut as a result of any patent, royalty payment or similar rights developing from any stem cell research made possible by the awarding of such grant-in-aid. Said committee shall direct the Commissioner of Public Health with respect awarding of the such grants-in-aid after considering recommendations from the Stem Cell Research Peer Review Committee established pursuant to section 4 of this act. 

(c) Commencing with the fiscal year ending June 30, 2006, and for each of the nine consecutive fiscal years thereafter, until the fiscal year ending June 30, 2015, not less than ten million dollars shall be made available from the Biomedical Research Trust Fund for grants-in-aid to eligible institutions for the purpose of conducting embryonic or human adult stem cell research, as directed by the Stem Cell Research Advisory Committee established pursuant to section 3 of this act. Any balance of such amount not used for such grants-in-aid during a fiscal year shall be carried forward for the fiscal year next succeeding for such grants-in-aid.

Sec. 3. (NEW) (Effective from passage) (a) There is established a Stem Cell Research Advisory Committee. The committee shall consist of the Commissioner of Public Health and eight members who shall be appointed as follows: Two by the Governor, one of whom shall be nationally recognized as an active investigator in the field of stem cell research and one of whom shall have background and experience in the field of bioethics; one each by the president pro tempore of the Senate and the speaker of the House of Representative, who shall have background and experience in private sector stem cell research and development; one each by the majority leaders of the Senate and House of Representatives, who shall be academic researchers specializing in stem cell research; and one each by the minority leaders

of the Senate and House of Representatives, who shall have 143 144 background and experience in either private or public sector stem cell 145 research and development or related research fields, including, but not limited to, embryology, genetics or cellular biology. Members shall 146 147 serve for a term of four years commencing on October first, except that 148 members first appointed by the Governor and the majority leaders of 149 the Senate and House of Representatives shall serve for a term of two 150 years. No member may serve for more than two consecutive four-year 151 terms and no member may serve concurrently on the Stem Cell 152 Research Peer Review Committee established pursuant to section 4 of 153 this act. All initial appointments to the committee shall be made by 154 October 1, 2005. Any vacancy shall be filled by the appointing 155 authority.

- 156 (b) The Commissioner of Public Health shall serve as the 157 chairperson of the committee and shall schedule the first meeting of 158 the committee, which shall be held no later than December 1, 2005.
- (c) All members appointed to the committee shall work to advance 160 embryonic and human adult stem cell research. Any member who fails to attend three consecutive meetings or who fails to attend fifty per cent of all meetings held during any calendar year shall be deemed to have resigned from the committee.
  - (d) All members shall be deemed public officials and shall adhere to the code of ethics for public officials set forth in chapter 10 of the general statutes. No member shall participate in the affairs of the committee with respect to the review or consideration of any grant-inaid application filed by such member or by any eligible institution in which such member has a financial interest, or with whom such member engages in any business, employment, transaction or professional activity.
- 172 (e) The Stem Cell Research Advisory Committee shall use the 173 moneys available for stem cell research in the Biomedical Research 174 Trust Fund pursuant to section 19a-32c of the general statutes, as

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amended by this act, for the purposes of (1) developing, in consultation with the Commissioner of Public Health, a donated funds program to encourage the development of funds other than state appropriations for embryonic and human adult stem cell research, (2) examining and identifying specific ways to improve and promote forprofit and not-for-profit embryonic and human adult stem cell and related research in the state, including, but not limited to, identifying both public and private funding sources for such research, maintaining existing embryonic and human adult stem cell related businesses, recruiting new embryonic and human adult stem cell related businesses to the state and recruiting scientists and researchers in such field to the state, (3) establishing and administering, in consultation with the Commissioner of Public Health, a stem cell research grant program which shall provide grants-in-aid to eligible institutions for the advancement of embryonic or human adult stem cell research pursuant to section 19a-32c of the general statutes, as amended by this act, and (4) monitoring the stem cell research conducted by eligible institutions that receive such grants-in-aid.

- (f) Connecticut Innovations, Incorporated shall serve as administrative staff of the committee and shall assist the committee in (1) developing the application for the grants-in-aid authorized under subsection (e) of this section, (2) reviewing such applications, (3) executing any assistance agreements or other agreements in connection with the awarding of such grants-in-aid, and (4) performing such other administrative duties as the committee deems necessary.
- (g) Not later than June 30, 2007, and annually thereafter until June 30, 2015, the Stem Cell Research Advisory Committee shall report, in accordance with section 11-4a of the general statutes, to the Governor and the General Assembly on (1) the amount of grants-in-aid awarded from the Biomedical Research Trust Fund pursuant to subsection (e) of this section for stem cell research, (2) the recipients of such grants-in-aid, and (3) the current status of stem cell research in the state.
- Sec. 4. (NEW) (Effective from passage) (a) There is established a Stem

Cell Research Peer Review Committee. The committee shall consist of five members appointed by the Commissioner of Public Health. All members appointed to the committee shall (1) have demonstrated knowledge and understanding of the ethical and medical implications of embryonic and human adult stem cell research or related research fields, including, but not limited to, embryology, genetics or cellular biology, (2) have practical research experience in human adult or embryonic stem cell research or related research fields, including, but not limited to, embryology, genetics or cellular biology, and (3) work to advance embryonic and adult stem cell research. Members shall serve for a term of four years commencing on October first, except that three members first appointed by the Commissioner of Public Health shall serve for a term of two years. No member may serve for more than two consecutive four-year terms and no member may serve concurrently on the Stem Cell Research Advisory Committee established pursuant to section 3 of this act. All initial appointments to the committee shall be made by October 1, 2005. Any member who fails to attend three consecutive meetings or who fails to attend fifty per cent of all meetings held during any calendar year shall be deemed to have resigned from the committee.

- (b) All members shall be deemed public officials and shall adhere to the code of ethics for public officials set forth in chapter 10 of the general statutes. No member shall participate in the affairs of the committee with respect to the review or consideration of any grant-inaid application filed by such member or by any eligible institution with whom such member has a financial interest in, or engages in any business, employment, transaction or professional activity.
- (c) Prior to the awarding of any grants-in-aid for embryonic or human adult stem cell research pursuant to section 3 of this act, the Stem Cell Research Peer Review Committee shall review all applications submitted by eligible institutions for such grants-in-aid and make recommendations to the Commissioner of Public Health and the Stem Cell Research Advisory Committee established pursuant to section 3 of this act with respect to the ethical and scientific merit of

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- 242 each application.
- 243 (d) The Peer Review Committee shall establish guidelines for the 244 rating and scoring of such applications by the Stem Cell Research Peer
- 245 Review Committee.
- (e) All members of the committee shall become and remain fully cognizant of the National Academies Guidelines For Human Embryonic Stem Cell Research, as from time to time amended, and the committee may make recommendations to the Stem Cell Research Advisory Committee and the Commissioner of Public Health concerning the adoption of said guidelines, in whole or in part, in the
- 252 form of regulations adopted pursuant to chapter 54 of the general
- 253 statutes.
- Sec. 5. Subsection (c) of section 4-28e of the general statutes is repealed and the following is substituted in lieu thereof (*Effective from*
- 256 passage):
- 257 (c) (1) For the fiscal year ending June 30, 2001, disbursements from
- 258 the Tobacco Settlement Fund shall be made as follows: (A) To the
- 259 General Fund in the amount identified as "Transfer from Tobacco
- 260 Settlement Fund" in the General Fund revenue schedule adopted by
- 261 the General Assembly; (B) to the Department of Mental Health and
- 262 Addiction Services for a grant to the regional action councils in the
- amount of five hundred thousand dollars; and (C) to the Tobacco and
- 264 Health Trust Fund in an amount equal to nineteen million five
- 265 hundred thousand dollars.
- 266 (2) For the fiscal year ending June 30, 2002, and each fiscal year
- 267 thereafter, disbursements from the Tobacco Settlement Fund shall be
- 268 made as follows: (A) To the Tobacco and Health Trust Fund in an
- amount equal to twelve million dollars; (B) to the Biomedical Research
- 270 Trust Fund in an amount equal to four million dollars; (C) to the
- 271 General Fund in the amount identified as "Transfer from Tobacco
- 272 Settlement Fund" in the General Fund revenue schedule adopted by
- 273 the General Assembly; and (D) any remainder to the Tobacco and

- 274 Health Trust Fund.
- 275 (3) For the fiscal year ending June 30, 2005, the sum of twenty 276 million dollars shall be disbursed from the Tobacco Settlement Fund to
- 277 the Biomedical Research Trust Fund, and shall be available for
- 278 <u>disbursement from the Biomedical Research Trust Fund, for embryonic</u>
- or human adult stem cell research, as follows: The sum of ten million
- dollars shall be available for the fiscal year ending June 30, 2006; the
- 281 sum of ten million dollars shall be available for the fiscal year ending
- 282 June 30, 2007.
- 283 (4) For each of the fiscal years ending June 30, 2008, to June 30, 2015,
- 284 <u>inclusive, the sum of ten million dollars shall be disbursed from the</u>
- 285 Tobacco Settlement Fund to the Biomedical Research Trust Fund, for
- 286 <u>embryonic or human adult stem cell research.</u>
- Sec. 6. (Effective from passage) The sum of twenty million dollars is
- 288 appropriated to the Tobacco Settlement Fund, from the General Fund,
- for the fiscal year ending June 30, 2005."

This act shall take effect as follows and shall amend the following sections:

Section 1	from passage	New section
Sec. 2	from passage	19a-32c
Sec. 3	from passage	New section
Sec. 4	from passage	New section
Sec. 5	from passage	4-28e(c)
Sec. 6	from passage	New section